IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

UNIMED PHARMACEUTICALS, INC., a Delaware corporation, and LABORATORIES BESINS ISCOVESCO, a Delaware corporation,	)	
Plaintiffs,	)	
v.	)	**Nos. 1:03-CV-2501 TWT** **1:03-CV-2503 TWT**
WATSON PHARMACEUTICALS, INC., a Nevada corporation, and PADDOCK LABORATORIES, INC., a Minnesota corporation,	)	
Defendants.	)	

PLAINTIFFS' CONSOLIDATED MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTIONS FOR PARTIAL SUMMARY JUDGMENT

Jerry B. Blackstock
HUNTON & WILLIAMS
4100 Bank of America Plaza
600 Peachtree Street NE
Atlanta, Georgia 30308-2216
Telephone: (404) 888-4000
Facsimile: (404) 888-4190

Of Counsel:
James R. Ferguson
Robert S. Rigg
MAYER, BROWN, ROWE & MAW LLP
71 South Wacker Drive
Chicago, Illinois 60606
Telephone: (312) 782-0600
Facsimile: (312) 701-7711

Attorneys for Plaintiffs
Unimed Pharmaceuticals, Inc. and
Laboratories Besins Iscovesco

October 17, 2005

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I. INTRODUCTION

This case involves a patent covering the formulation for a transdermal testosterone gel known as AndroGel®. Defendants have filed summary judgment motions challenging the validity of a Certificate of Correction issued by the Patent and Trademark Office ("PTO") for the patent in suit. In the Certificate, the PTO corrected the patent claims by adding a term ("0.1 N") that had been mistakenly omitted from the ranges of sodium hydroxide in the claimed formulation.

Under controlling Federal Circuit law, the Certificate of Correction cannot be set aside unless Defendants can show by clear and convincing evidence that one skilled in the art would not recognize the error or understand how to correct it based on a reading of the patent. Nevertheless, Defendants now argue that this issue raises no genuine disputes of material fact. This argument should be rejected for at least three reasons.

First, Defendants ignore the relevant standard by failing to submit any evidence showing how one skilled in the art would understand both the claimed error and the patent in suit. Instead, Defendants rely entirely on a series of attorney arguments that purport to interpret certain aspects of the prosecution history, with no attempt at even identifying who the relevant "person of ordinary skill in the art" should be. It is well settled that attorney argument is no substitute for competent

evidence, and that all justifiable inferences must be drawn in favor of the non-movant on summary judgment. In this case, Defendants' summary judgment motions violate both principles.

Second, Defendants ignore the entire body of Plaintiffs' evidence showing that a skilled artisan would recognize both the nature of the error and how it should appropriately be corrected. This evidence (which includes the testimony of two highly-regarded experts in pharmaceutical science, as well as the admissions of Defendants' own scientists) shows that a skilled artisan would recognize that the original concentrations of sodium hydroxide are far too caustic to be used on human skin. The same evidence also shows that such an artisan would recognize that the error could appropriately be corrected by inserting the term "0.1 N" which is disclosed in the specification of the patent. This, indeed, is the only value for the sodium hydroxide concentration that is expressly disclosed in the specification, which the Federal Circuit describes as the "single most reliable guide" to the meaning of claims.

Third, even if Defendants' attorney arguments could somehow be viewed as evidence, it would serve only to underscore the material factual disputes created by Plaintiffs' evidence. The Federal Circuit has repeatedly held that issues involving

differences of expert credibility or scientific opinion cannot be resolved on summary judgment.

Finally, Paddock argues that the Certificate of Correction does not apply to this case because the PTO issued the Certificate after Plaintiffs filed their complaints. However, this argument ignores the nature of Plaintiffs' action, which is brought under the Hatch-Waxman Act, and thus involves an "infringement that will happen in the future." For this reason, the Court must determine whether Defendants' *future* sales will infringe the then-existing patent – *i.e.*, the patent as corrected by the Certificate of Correction. In addition, Paddock's argument ignores the nature of patent infringement as a continuing tort. The Federal Circuit has made clear that a "continuing disregard of the legal rights of the patentee" provides an adequate factual foundation for an infringement action.

Each of these points is developed below.

II. THE CLAIMED INVENTION

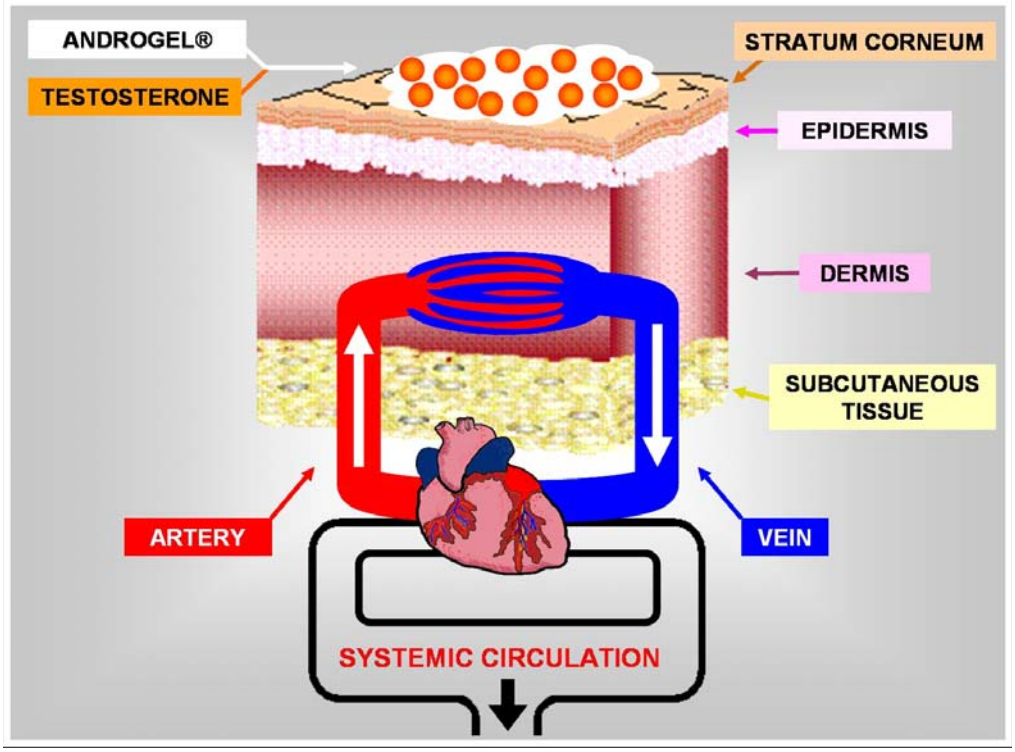
A. AndroGel® and the Prior Art "Skin Patches"

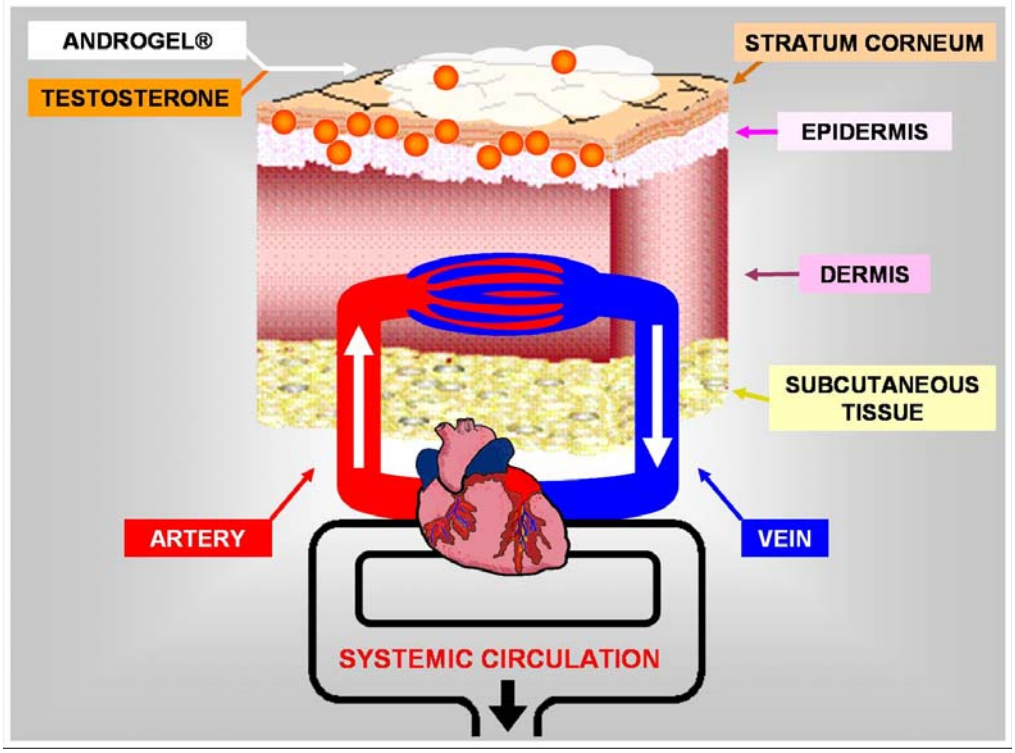
AndroGel® is the first testosterone gel ever approved by the FDA, and the first gel ever shown to produce normal levels of testosterone in hypogonadal men over a sustained period. Male hypogonadism is a chronic clinical condition that affects an estimated 4 million men in the United States, and it is characterized by low levels of serum testosterone and a variety of symptoms. (Ex. B, at 5-6).

Prior to the development of AndroGel®, physicians relied primarily on testosterone injections or transdermal patches to increase serum testosterone levels in hypogonadal patients. The testosterone patches utilize an external, "rate-limiting membrane" to regulate both the rate of delivery and the quantity of testosterone that penetrates the skin. (Ex. C, at ¶ 21-23). The rate-limiting membrane is a key feature of the patch system because it prevents the testosterone from being immediately absorbed into the skin and then traveling directly to the bloodstream. (*Id.*). If the testosterone is immediately absorbed into the bloodstream, the patient receives only a few hours of benefit because of testosterone's short half-life (approximately 60 minutes) in the body. (*Id.*).

In contrast to the patch, AndroGel® is a testosterone gel that does *not* utilize an external, rate-limiting membrane. (*Id.*). Instead, AndroGel® surprisingly

facilitates the ability of the skin to act as its own "patch" by retaining the testosterone in the outer layer known as the stratum corneum. (*Id.*). In particular, AndroGel® enables testosterone to penetrate into the stratum corneum and then remain within that layer, so that the stratum corneum becomes a kind of "reservoir" for the hormone. (*Id.*). Ultimately, the testosterone begins to slowly diffuse through the remaining layers of the skin and into the circulatory system where it is then transported to other areas of the body. (*Id.*). The formulation thus produces a prolonged release of testosterone into the bloodstream – *i.e.*, a sustained-release effect – as shown below:


ANDROGEL®
TESTOSTERONE
STRATUM CORNEUM
EPIDERMIS
DERMIS
SUBCUTANEOUS TISSUE
ARTERY
VEIN
SYSTEMIC CIRCULATION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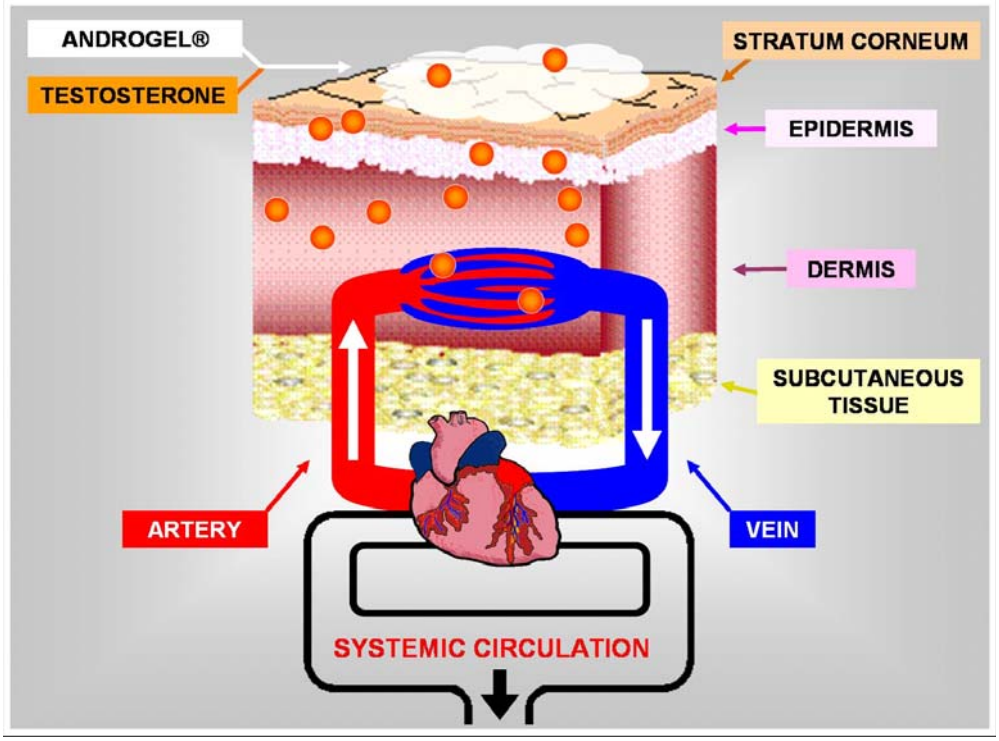
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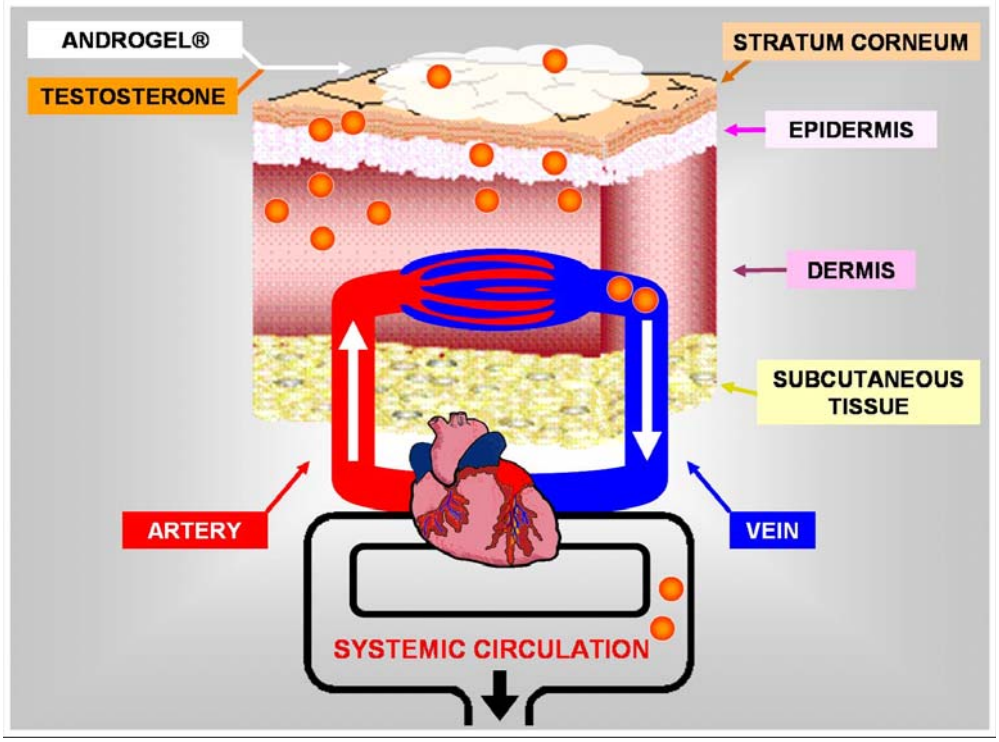
ANDROGEL®
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B. "Steady State" Testosterone Levels: The Clinical Trial Evidence

In clinical trials on hypogonadal men, AndroGel® was shown to produce "steady-state" testosterone levels within the normal physiologic range over a sustained period of time. (Ex. A, 14:25-25:48). The maintenance of this "steady-state" profile over a prolonged treatment period represented a remarkable technological achievement. (Ex. C, at ¶ 23). It showed that the daily use of AndroGel® not only *increased* testosterone to normal levels, but also *maintained* those levels by replacing testosterone at approximately the same rate as the hormone was being used (and eliminated) by the body. (*Id.*). If the formulation had produced testosterone levels below the normal range (*i.e.*, "sub-therapeutic" levels), it would have had no clinical value in the treatment of hypogonadal patients. Conversely, if the formulation had produced levels materially above the normal range (*i.e.*, "supraphysiologic" levels), it would have raised significant questions of safety. (Ex. E, at ¶¶ 54-60). Indeed, just two years ago, the FDA rejected the application of a competitive testosterone gel because it produced supraphysiologic levels of testosterone that could not be safely managed through dose titration. (*Id.*).

C. The AndroGel® Formulation

AndroGel®'s ability to achieve and maintain "steady-state" testosterone levels over a prolonged treatment period is a direct result of its novel formulation. In that formulation, an active ingredient (testosterone) is administered transdermally through a combination of an alcohol (ethanol) and a so-called "penetration enhancer" known as isopropyl myristate. (Ex. C, at ¶ 14). This penetration-enhancing system is directly responsible for the steady-state blood levels that result from the daily administration of AndroGel®. (*Id.*). The AndroGel® formulation is administered in the form of a gel which results when sodium hydroxide (NaOH) neutralizes a gelling agent in the presence of water. The formulation thus consists of six ingredients in the following concentrations:

AndroGel®

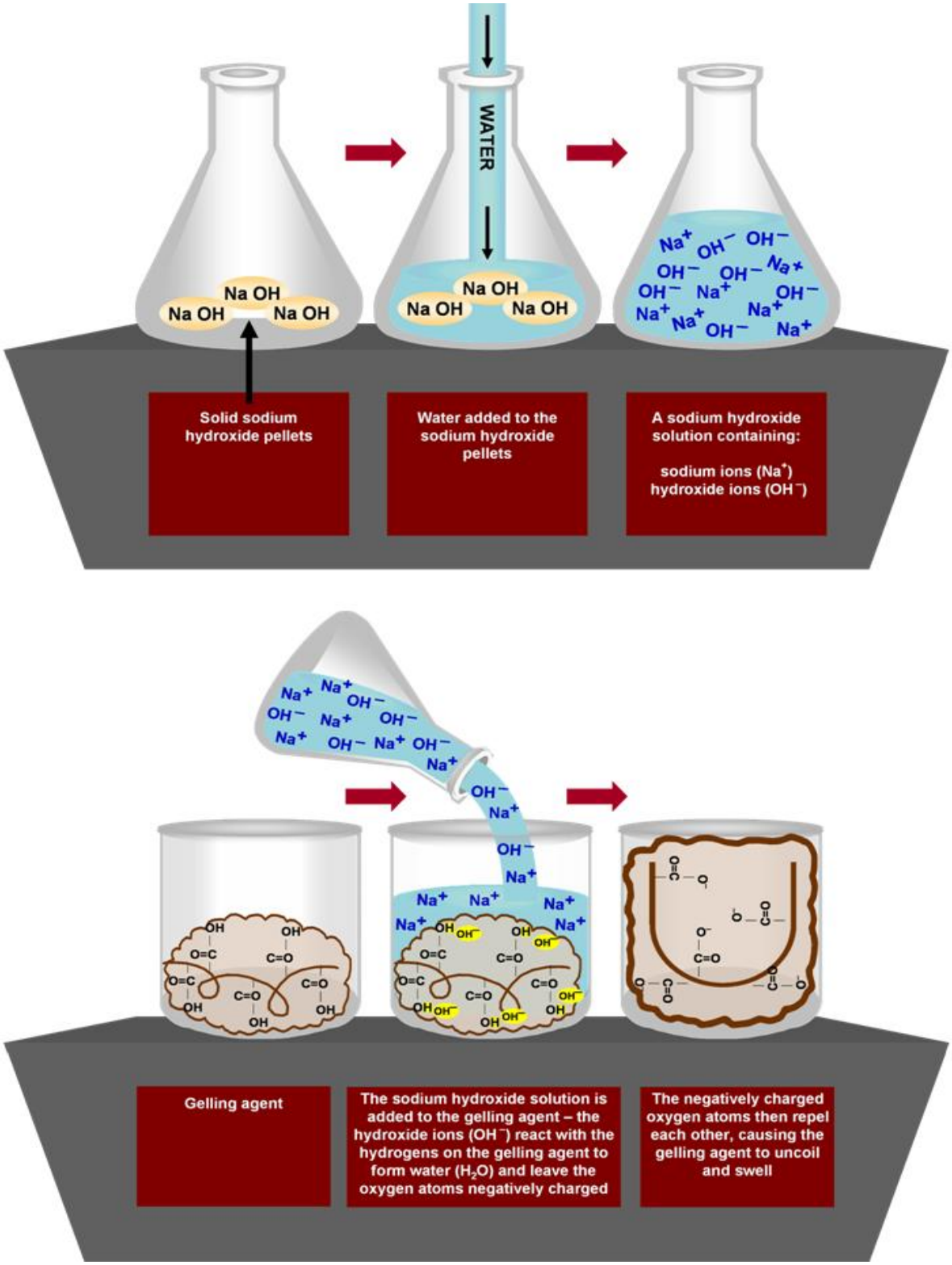
Testosterone	1%
Alcohol (Ethanol)	72.5%
Isopropyl Myristate	0.5%
0.1 N NaOH	4.72%
Gelling Agent	0.9%
Water	20.38%

(Ex. A, 13:25-35). A person skilled in the art would recognize that the concentrations of the above constituents could be varied within specific ranges and

still serve the intended purpose of the invention. (*Id*., 13:36-43). These ranges are the subject of the claims of the '894 Patent.

D. Sodium Hydroxide

Defendants' summary judgment motions challenge a PTO Certificate of Correction that corrected the concentration of sodium hydroxide in the claimed formulation. In that formulation, the sodium hydroxide is used to cause the formation of a gel by neutralizing a so-called "gelling agent." (Ex. M, at ¶ 7). This occurs when the sodium hydroxide is mixed in an aqueous (*i.e.*, water-based) solution that causes the sodium hydroxide to dissociate into charged molecules called "ions" (NA^+ and OH^-). (*Id*.). The OH^- ions then neutralize the molecules of the gelling agent, which leads to a lengthening of the molecules and the formation of a uniform gel. (*Id*.). This chemical reaction is depicted below:


WATER
Na OH
Na OH
Na OH
Na OH
Na OH
Na OH
Solid sodium hydroxide pellets
Water added to the sodium hydroxide pellets
A sodium hydroxide solution containing:
sodium ions (Na+)
hydroxide ions (OH−)
Gelling agent
The sodium hydroxide solution is added to the gelling agent – the hydroxide ions (OH−) react with the hydrogens on the gelling agent to form water (H2O) and leave the oxygen atoms negatively charged
The negatively charged oxygen atoms then repel each other, causing the gelling agent to uncoil and swell

A "0.1 N" solution of sodium hydroxide and water is a highly diluted solution that is frequently used in pharmaceutical practice.[1] (Ex. F, at ¶ 17). In this case, the range of 0.1 N sodium hydroxide solution specified in the corrected patent claims (*i.e.*, "about 1% to 5%" or "about 1% to about 3%") represents the range of the concentration of the solution needed to neutralize the corresponding range of gelling agent specified in the same claims. (*Id.*). If a materially greater amount of sodium hydroxide were used in the solution, it would prevent the formation of the gel and produce a caustic solution that could "rapidly destroy tissues." (Ex. S, at 1047).

III. THE PATENT IN SUIT

The '894 Patent is directed to a pharmaceutical composition comprising testosterone in a gel formulation and to methods of using the composition. In Table 5, the specification expressly sets forth the AndroGel® formulation as a preferred embodiment of the claimed invention. (Ex. A., 13:25-35). In addition, the specification contains 18 pages of clinical data and 40 tables, figures and

[1] The term "N" means normality, which is defined as the number of equivalents of solute per liter of solution. (Ex. V, at 348). One equivalent of sodium hydroxide (the solute) consists of 40 grams of sodium hydroxide. As a result, a 0.1 N solution consists of four grams of pure sodium hydroxide dissolved in one liter of water.

drawings based on clinical trials testing the safety and efficacy of AndroGel®. (*Id*., 14:25-49:20).

The claims of the '894 Patent fall into two broad categories: Claims 1-17 are directed to the pharmaceutical composition, and Claims 18-42 are directed to methods for using the composition. The method claims disclose specific blood levels of testosterone resulting from a daily dose of the composition. (*Id*., 51:1-52:60). In general, the method claims recite the same compositions set forth in the formulation claims, except for Claims 31-42, which do not recite sodium hydroxide as a required element. (*Id*., 52:3-23). As a result, Defendants' motions for partial summary judgment do not affect Claims 31-42.

IV. THE CERTIFICATE OF CORRECTION

The sole issue raised by Defendants' summary judgment motions is the validity of a Certificate of Correction issued by the PTO for the '894 Patent. (Ex. H). In that Certificate, the PTO corrected an error in the concentration of the sodium hydroxide ranges set forth in the claimed formulation. This issue affects Claims 1-30 of the patent (which recite sodium hydroxide as a required element), but it does not affect Claims 31-42 (which do not recite sodium hydroxide as a required element).

The PTO issued the Certificate following the discovery of an error contained in some amended claims submitted during the prosecution of the patent application. The amended claims attempted to recite a range of sodium hydroxide that included the sodium hydroxide concentration in the AndroGel® formulation, as set forth in Table 5 of the specification. (Ex. I). In that table, the specification described the relevant concentration using the term "0.1 N" to show a concentration of sodium hydroxide in water. (Ex. A, 13:32).

However, the amended claims erroneously omitted the term "0.1 N" before the phrase "sodium hydroxide" in the claimed ranges of sodium hydroxide. As a result, the originally-issued patent contained four independent claims (Claims 1, 9, 10 and 18) that recited a concentration of "about 1% to about 5%" (or "about 1% to about 3%") of sodium hydroxide – amounts that would be extremely caustic if applied to human skin in undiluted concentrations. (Ex. F, at ¶ 20).

After discovering this error – but *before* learning of Defendants' plans to challenge the patent[2] – the applicants filed a request for a Certificate of Correction. (Ex. O). The applicants thereafter discussed the correction of the error with the Examiner (who is presumed by law to act from the viewpoint of a person of

[2] Plaintiffs filed their request for the Certificate of Correction on June 12, 2003, and they received notice that Defendants were seeking FDA approval to sell generic versions of AndroGel® on July 7, 2003. (*See* Ex. O).

ordinary skill in the art). (Ex. BB); *In re Sang-Su Lee*, 277 F.3d 1338, 1345 (Fed. Cir. 2002). On December 16, 2003, the PTO issued a certificate which corrected the error by adding the term "0.1 N" before the phrase "sodium hydroxide" in Claims 1, 9, 10 and 18. (Ex. H).

V. GOVERNING LEGAL PRINCIPLES

A. Summary Judgment

Summary judgment is appropriate only if the moving party can prove that the evidence raises no genuine issue of material fact. Fed. R. Civ. P. 56 (c). In deciding a summary judgment motion, the court must view the evidence in the light most favorable to the non-movant, drawing all justifiable inferences in the non-movant's favor and giving due respect to the *moving party's substantive burden of proof*. *Anderson v. Liberty Lobby*, 477 U.S. 242, 255 (1986); *Rockwell Int'l Corp. v. United States*, 147 F.3d 1358, 1361-62 (Fed. Cir. 1998).

B. Burden of Proof: Clear and Convincing Evidence

The law is clear that the "clear and convincing" evidence standard applies to all challenges to the validity of Certificates of Correction. *Superior Fireplace Co. v. Majestic Products Co.*, 270 F.3d 1358, 1367 (Fed. Cir. 2001). This rigorous standard reflects the courts' recognition that the PTO is presumed to have properly "done its job" in the issuance of Certificates of Correction. *Id*. at n.1.

Consequently, on summary judgment, Defendants must show not only that the material facts are undisputed, but also that the undisputed facts provide clear and convincing evidence that the PTO erroneously issued the challenged Certificate. *Anderson*, 477 U.S. at 255.

C. Challenges to the Validity of Certificates of Correction

In a series of recent decisions, the Federal Circuit has held that 35 U.S.C. § 255 authorizes the Director of the PTO to make certain "broadening corrections"[3] of ministerial errors in the language of patent claims. *Arthrocare Corp. v. Smith & Nephew, Inc.*, 406 F.3d 1365, 1375 (Fed. Cir. 2005); *Superior Fireplace*, 270 F.3d at 1371. Under these decisions, a court must uphold such a correction unless the accused infringer can show by clear and convincing evidence that a person of ordinary skill in the art would not recognize the nature of the error or the way in which it should "appropriately be corrected." *Arthrocare*, 406 F.3d at 1375.

In applying this test, the Federal Circuit has made clear that the key inquiry focuses on the way in which a "person of ordinary skill in the art" would

[3] Although the correction in this case actually results in a far *narrower* range of sodium hydroxide, it nevertheless falls within the Federal Circuit's definition of "broadening" because the new, narrower range was not contained in the original range. *Schering Corp. v. Amgen, Inc.*, 222 F.3d 1347, 1352 (Fed. Cir. 2000).

understand both the claimed error and the intrinsic record of the patent – *i.e.*, the claims, the specification and the prosecution history. *Id*.

For example, in *Arthrocare*, the Court upheld the validity of a Certificate of Correction after carefully reviewing the way in which "one of skill in the art" would understand the error in light of the patent's "specification, drawings and the prosecution history." *Id*. The Court first noted that a skilled artisan would immediately recognize that the patent contained a "ministerial error" since the language of the claims, if uncorrected, would not "make sense" and would defeat the "whole point of the patent." *Id*., at 1374-75. The Court then found that the specification and prosecution history would provide a skilled artisan with clear guidance on how the error should appropriately be corrected. *Id*. For these reasons, the Court held that the record did not show by clear and convincing evidence that a "person of ordinary skill in the art would not understand how to correct [the] errors." *Id.* at 1375.

Accordingly, under the Federal Circuit's standard, the validity of the Certificate of Correction in this case turns ultimately on a question of fact: Can Defendants show by clear and convincing evidence that "one skilled in the art" who reviewed the intrinsic record would not understand the nature of the error or

how it should "appropriately be corrected"? This factual issue provides the analytical framework for resolving Defendants' motions.

VI. DEFENDANTS RELY ENTIRELY ON ATTORNEY ARGUMENT

Before turning to the merits, it is first necessary to address the nature of the "evidence" submitted by Defendants in support of their summary judgment motions. As shown above, the validity of a Certificate of Correction does not present an abstract question of law that can be resolved without considering the evidence of record. Instead, it raises a question of fact that focuses on the way in which one skilled in the art would understand the claimed error in light of the intrinsic record. Yet, in their respective memoranda, Defendants cite *no* evidence showing how a skilled artisan would understand either the claimed error or the intrinsic record, even though Defendants now seek summary judgment on this very issue.

Instead, Defendants rely entirely on a series of attorney arguments that purport to interpret certain aspects of the prosecution history, with no attempt at even identifying who the relevant "person of ordinary skill in the art" should be. For example, relying entirely on attorney argument (and drawing all inferences *against* the non-movant Plaintiffs), Defendants assert that the prosecution history allegedly shows that (1) the error in the original sodium hydroxide concentrations

was "not obvious"; (2) the applicants "apparently" intended to claim pure sodium hydroxide; and (3) the applicants "evidently" derived the sodium hydroxide ranges from an erroneous conversion calculation. (Watson Br., at 20-21; Paddock Br., at 12-13, 31-32, 34). At no point, however, do Defendants cite any evidence showing how a *skilled artisan* would read the same intrinsic record. Indeed, Defendants do not even cite the testimony of their own experts – or their own fact witness employees – to support their attorney arguments on the sodium hydroxide issue.[4]

It is well settled that attorney argument is no substitute for competent evidence, particularly when such arguments are used to support a motion for summary judgment. *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1581 (Fed. Cir. 1989). It is equally well settled that, on summary judgment, all justifiable inferences must be drawn in favor of the non-movant. *Rockwell*, 147 F.3d at 1361-62. In this case, Defendants' summary judgment motions violate both principles, while failing to cite *any* substantive evidence showing how a skilled artisan would understand either the claimed error or the intrinsic record. For these reasons alone, the summary judgment motions should be denied.

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[4] In its substantive argument, Watson nowhere cites the reports or testimony of any its expert witnesses or its own fact witness employees. (*See generally* Watson Br.). Paddock also does not cite the testimony of its own employees and makes only passing references to its experts' reports for three minor points. (Paddock Br., at 9, 14, 18, and 37).

VII. DEFENDANTS' ARGUMENTS DO NOT ADDRESS PLAINTIFFS' EVIDENCE

In addition to their reliance on attorney argument, Defendants fail to address any of Plaintiffs' evidence showing that a skilled artisan would recognize both the nature of the error and how it should "appropriately be corrected."

This evidence includes the detailed reports and affidavits of two well-known and highly-regarded experts in pharmaceutical science – Dr. Christopher Bowman of the University of Colorado (currently on sabbatical at M.I.T.), and Dr. Norman Weiner of the University of Michigan – who have a combined total of more than 40 years of experience in the chemical and pharmaceutical fields. (Exs. L, M; *see also* Exs. D, E, F and P). The evidence also includes the admissions of Defendants' own scientists, who, like the PTO, recognized that the original concentrations of sodium hydroxide could not possibly be correct. (Exs. G, Q, R).

Nowhere in their briefs do Defendants discuss any of this evidence, even though it directly refutes each of their major factual assertions. As a result, this evidence provides a wholly independent ground for denying the summary judgment motions.

A. The Relevant "Person of Ordinary Skill in the Art"

As noted earlier, the Federal Circuit has made clear that the validity of a Certificate of Correction must be assessed from the perspective of "one skilled in

the art." *Arthrocare*, 406 F.3d at 1375. Accordingly, it is first necessary to identify the substantive area of skill relevant to the issues raised by Defendants' motions, even though Defendants nowhere address this topic in their briefs.

In this case, the Certificate of Correction relates to the concentration of sodium hydroxide in a formulation for a pharmaceutical product. As a result, the relevant "person skilled in the art" is an individual with a degree in chemistry or pharmaceutical sciences who has had at least 1-2 years of experience in developing gels, creams, lotions or other similar delivery forms for human applications. (Ex. F, at 2-3). Consistent with this definition, Plaintiffs will refer to the relevant skilled artisan as a "skilled chemist."

B. A Skilled Chemist Would Recognize That The Original Sodium Hydroxide Concentration Was a Clerical or Ministerial Error

Defendants first argue that the original sodium hydroxide concentration was not clearly a ministerial error because the patent claims allegedly "made sense" without the correction. (Watson Br., at 18). To support this assertion, Defendants note that the request to correct the error was not submitted until more than a year after first filing an amendment containing the erroneous concentration. (*Id*., at 19-20).

This argument fails for several reasons. First, the argument ignores the relevant standard, which is whether the error would be clearly evident to "one

skilled in the art" – and not whether it would be clearly evident to the attorney who prosecuted the original patent application. The Federal Circuit has squarely held that the mere fact that a prosecuting attorney makes errors in drafting a patent – and thereafter fails to detect the errors – "does not demonstrate by clear and convincing evidence that a person of ordinary skill in the art would not understand how to correct those errors." *Arthrocare*, 406 F.3d at 1375. Indeed, in *Arthrocare*, the Court upheld the validity of a Certificate of Correction even though the Certificate did not correct some errors that the prosecuting attorney had failed to detect when he submitted the request for the Certificate. *Id.*

More importantly – and consistent with the relevant standard – the testimony of Plaintiffs' experts shows that a person skilled in the relevant art *would* clearly recognize that the original concentrations of sodium hydroxide were a ministerial error. Indeed, in their affidavits and expert reports, Dr. Bowman and Dr. Weiner identify three independent reasons why a person skilled in pharmaceutical chemistry would recognize that the original sodium hydroxide concentrations were mistaken.

First, such a chemist would immediately see that the concentration in the uncorrected claims is *50 to 250 times* greater than the correct concentration in the

preferred embodiment of AndroGel®, as set forth in Table 5 of the specification. [5] Without more, the enormity of this discrepancy would demonstrate to anyone skilled in pharmaceutical chemistry that the original concentrations could not possibly be correct. (Exs. E, at 2-3; G, at 88-89; M, at ¶ 4).

Second, a skilled chemist would also recognize that a concentration of "about 1% to about 5%" of pure sodium hydroxide is far too caustic to be used in the claimed formulation for a transdermal gel. (Ex. D, ¶ 44; Ex. M., at ¶ 5). Indeed, such a concentration would not "make sense" because it would defeat the "whole point of the patent" — the *transdermal* administration of testosterone. *Arthrocare*, 403 F.3d at 1375. This conclusion comports with the teaching of a leading pharmaceutical reference (cited in the patent) which describes sodium hydroxide as "caustic soda" and cautions practitioners to "exercise great care in handling it, *as it rapidly destroys tissues*." *Remington*: *The Science and Practice of Pharmacy*, at 1047 (20th Ed.) (emphasis added). (Ex. S).

Third, a skilled chemist would also recognize that the sodium hydroxide limitations in the original patent must refer to a sodium hydroxide solution. (Ex. L, at ¶ 3; Ex. M, at ¶ 3). As noted earlier, the gelling process takes place when

[5] The correct amount of pure sodium hydroxide added in the AndroGel® formulation is slightly less than 0.02% (0.018%), which is 50 to 250 times less than the range of "1% to 5%" in the issued claims.

sodium hydroxide is mixed in an aqueous solution to (1) dissociate the sodium hydroxide into ions so that the gelling agent can be neutralized; and (2) achieve an even distribution of ions which will produce a uniform clear gel. (Ex. M, at ¶¶ 7-8). This is precisely why the technical literature expressly teaches that "water systems" should be used whenever sodium hydroxide is used to neutralize a gelling agent. (Ex. M, at ¶ 8).

Nor are Plaintiffs' experts the only chemists who reached these conclusions. Defendants' own scientists also recognized that the sodium hydroxide limitation in the original patent must refer to a sodium hydroxide *solution* because otherwise the concentration would be far too caustic for use in a transdermal gel. (Ex. G, at 89). Indeed, the principal chemist in the development of Paddock's generic product wrote the notation "in solution?" next to the original patent claims because he recognized that the listed concentrations would destroy human tissue:

> Q. If you had 5% sodium hydroxide in a gel that was going to be applied to the human skin, would you expect there to be some side effects to that?
>
> A. If it was straight sodium hydroxide, yes.
>
> Q. It would burn the skin?
>
> A. Yes.
>
> Q. That's why you questioned originally whether it meant solution?

A. Correct.

(Ex. G, at 89). Accordingly, Paddock's scientific group concluded that Paddock's proposed generic copy of AndroGel® would infringe the claims of the originally-issued patent, notwithstanding the obviously incorrect concentration of sodium hydroxide:

> Q. You made a determination that, "It seems unlikely that we would be able to get around the patent from our perspective." Do you see that?
>
> A. *From a scientific perspective, I looked at the claims and determined that there was no other conclusion I could make . . .*

(Ex. Q, at 82) (emphasis added). Similarly, Watson's Rule 30(b)(6) witness concluded that Watson's generic copy of AndroGel® fell within the scope of the patent, notwithstanding the error in the sodium hydroxide concentration. (Ex. R, at 138).

This testimony provides powerful, pre-litigation, "real world" evidence that a skilled chemist would clearly recognize that the original sodium hydroxide limitation was a clerical or ministerial error. This conclusion is corroborated by the fact that Paddock made *exactly the same ministerial error* – omitting the term "0.1 N" – in its own statement of material facts supporting its summary judgment

motion.[6] Finally, the above testimony shows that, notwithstanding the error, "reasonable competitors" had sufficient notice of the scope of the patent to realize that they were engaging in potentially infringing activities. *Southwest Software, Inc. v. Harlequin, Inc.*, 226 F.3d 1280, 1295 (Fed. Cir. 2000). Defendants' arguments to the contrary are refuted by their own witnesses.

C. A Skilled Chemist Would Understand How the Error Should Appropriately Be Corrected

Defendants also argue that the addition of the term "0.1 N" was not a "clearly evident" way to correct the erroneous language in the original claims. In particular, Defendants assert that there is "no magic" in the selection of the term "0.1 N" since an aqueous solution of 0.1 N sodium hydroxide can be expressed in a variety of ways. (Watson Br., at 19; Paddock Br., at 34-37). Defendants further argue that a mathematical error made during prosecution indicates that (1) the applicants "apparently" intended to claim "pure" sodium hydroxide; (2) the claimed ranges of sodium hydroxide "evidently" resulted from this error; and (3) the addition of the term "0.1 N" did not correct the mathematical error. (Watson Br., at 20-21; Paddock Br., at 12-13, 31-32, 34).

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[6] *See* Paddock's "Statement of Material Facts as to Which There Are No Genuine Issues to Be Tried," at 6 (No. 25).

Once again, however, Defendants make these arguments without using the proper "skilled artisan" standard and without addressing any of Plaintiffs' expert testimony or fact witness evidence. Indeed, Defendants do not even correctly define the relevant issue, which is whether a skilled chemist would understand how the erroneous language in the *claims (i.e.,* "about 1% to about 5% sodium hydroxide"*)* should appropriately be corrected — and not how an error made during the prosecution history should appropriately be corrected.

On this issue, the testimony of Plaintiffs' experts shows that a skilled chemist would understand that the range of "about 1% to about 5% sodium hydroxide" should "appropriately be corrected" by adding the term "0.1 N." The experts base this conclusion on several factors.

First, a skilled chemist would recognize that "0.1 N" is the concentration disclosed in the specification which sets forth the formulation of AndroGel®, the preferred embodiment of the claimed invention:

Testosterone	1%
Alcohol (Ethanol)	72.5%
Isopropyl Myristate	0.5%
0.1 N NaOH	4.72%
Gelling Agent	0.9%
Water	20.38%

(Ex. A, 13:32). Indeed "0.1N" is the *only* value expressly cited by the specification for the concentration of the sodium hydroxide solution. (*Id.*).

Accordingly, as Plaintiffs' experts explain, the fact that the sodium hydroxide concentration in AndroGel® can be expressed in equivalent ways, while relevant to the infringement analysis, is not relevant to how a skilled chemist would correct the error in the claims. (Ex. W, at 175-79). Rather, such a chemist would select the normality set forth in the specification ("0.1 N") — and *not* some unspecified equivalent concentration — as the "appropriate" way (and indeed the only way) to correct the error. (Ex. E, at ¶ 7). This is particularly true since the resulting range of "about 1% to about 5% 0.1N sodium hydroxide" includes the sodium hydroxide concentration in the preferred embodiment of the invention.[7]

[7] The sodium hydroxide concentration in AndroGel® is 4.72% of 0.1 N solution, which plainly falls within the corrected range of "about 1% to about 5%" 0.1 N solution.

(*Id.*) Such an approach is consistent with recent Federal Circuit decisions holding that the specification is the "single best guide" to the meaning of patent claims. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (*en banc*).

Second, a skilled chemist would recognize that the corrected range of about "1% to about 5%" (or "about 1% to about 3%") 0.1 N represents the proper range for neutralizing the corresponding amounts of gelling agent specified in the patent claims. (Ex. P, at ¶¶ 26-42). Indeed, if the range included larger concentrations of sodium hydroxide, it would prevent the formation of the gel and produce a solution that was too caustic for human use. (*Id.*, at ¶ 47).

This evidence refutes Defendants' attorney argument that the claimed ranges of sodium hydroxide "evidently" resulted from the error in converting the original concentration in AndroGel® to pure sodium hydroxide. (Watson Br., at 21-21; Paddock Br., at 12-13, 31-32, 34). As the above evidence makes clear, Defendants' theory cannot explain why the allegedly "botched" ranges, when corrected by the simple addition of "0.1 N," just happen to cover the correct concentrations for neutralizing the specified amounts of gelling agent.

Third, a skilled chemist would recognize that the "0.1 N" correction is consistent with the prosecution history, which shows that both the applicants and the PTO understood the patent to claim the AndroGel® formulation. *See Phillips*,

415 F.3d at 1317 (prosecution history can provide "evidence of how the PTO and the inventor understood the patent"). The PTO Examiner plainly understood the patent to cover AndroGel® since she initially rejected all of the claims on the ground that the clinical trials of *AndroGel*® constituted an invalidating "public use" – a rejection that would make no sense if the Examiner (who is presumed by law to act from the viewpoint of a skilled artisan)[8] did not understand the claims to cover AndroGel®. (Ex. N, at 3). The applicants similarly understood the patent to cover AndroGel® since they overcame the Examiner's objections by showing that the AndroGel® trials fell within the "experimental use" exception to the "public use" doctrine. (Ex. I, at 24-26).

Defendants rely on a single statement in the voluminous prosecution history which miscalculated the amount of sodium hydroxide in the AndroGel® formulation. (Ex. I, at 26). However, this singular focus completely ignores the entire subject matter of both the patent and its prosecution history, namely, AndroGel® and gels similar to AndroGel®. Defendants provide no scientific evidence – and no testimony from one skilled in the art – as to why a conversion error would cause a skilled chemist to ignore the clear teachings of both the specification and the AndroGel® formulation. By contrast, Plaintiffs' expert has

[8] *Sang-Su Lee*, 277 F.3d at 1345.

shown that a skilled chemist would view the conversion error as "meaningless" and "irrelevant" in light of the specification and the entire prosecution history. (Ex. W, at 181-86).

Defendants also note that the corrected range of sodium hydroxide in one of the claims ("about 1% to about 3%" in Claim 9) does not literally cover the concentration in AndroGel®. (Paddock Br., at 13, 15, 32, 36). But as Plaintiffs' experts point out, the range in every other corrected claim does cover the sodium hydroxide concentration in AndroGel®. Defendants nowhere explain exactly why the Certificate of Correction should be set aside because *one* of the 30 corrected claims does not literally cover the preferred embodiment. Although a patent should not be construed to exclude its preferred embodiment, *Vitronics Corp., v. Concentronic, Inc.,* 90 F.3d 1583 (Fed. Cir. 1996), this does not mean that every claim in the patent *must* cover a preferred embodiment. Rather, the law is clear that a patent can contain some claims that are not limited to preferred embodiments, even when the specification discloses only one such embodiment. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004); *SRI Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985). Defendants' arguments to the contrary are without merit.

Thus, as Plaintiffs' experts show, based on all these factors, a skilled chemist would understand that the erroneous range of "about 1% to about 5%" (or "about 1% to about 3%") sodium hydroxide should appropriately be corrected by adding the omitted term of "0.1 N." Defendants make no mention of any of this evidence even though it is directly contrary to each of their assertions.

VIII. PLAINTIFFS' EVIDENCE RAISES DISPUTED FACTUAL ISSUES

As shown above, in their opening briefs, Defendants failed to submit any substantive evidence showing how one skilled in the art would understand either the claimed error or the '894 Patent. However, even if Defendants' attorney arguments could somehow be viewed as evidence — or even if Defendants could submit new evidence in their reply briefs[9] — such evidence would serve only to underscore the material factual disputes created by Plaintiffs' evidence. This conflict between Defendants' arguments and Plaintiffs' evidence can be summarized as follows:

[9] The law is clear that a summary judgment movant cannot submit new evidence (or new arguments) in its reply brief. *See ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 551 (Fed. Cir. 1998); *Lewis v. Zilog*, 908 F.Supp. 931, 959 (N.D.Ga. 1995); *United States v. Georgia Dept. of Nat'l Res.*, 897 F. Supp. 1464 (N.D. Ga. 1995).

FACTUAL ISSUE	DEFENDANTS' EVIDENCE	PLAINTIFFS' EVIDENCE
Would it be "clearly evident" to a skilled chemist that the patent contained an error?	Attorney Argument (Watson Br., at 18-19); Paddock Br., at 30-33)	Dr. Bowman Report, Affidavit; Dr. Weiner Reports, Affidavit; Paddock deposition (Zeleny). (Exs. D, E, F, G, L, M, P)
— Did the original concentration "make sense"?	Attorney Argument (Watson Br., at 18)	Dr. Bowman Report, Affidavit; Dr. Weiner Reports, Affidavit; Paddock deposition (Zeleny). (Exs. D, E, F, G, L, M, P)
— Was the original concentration too caustic for use on human skin?	None	Dr. Bowman Report, Affidavit; Dr. Weiner Reports, Affidavit; Paddock deposition (Zeleny). (Exs. D, E, F, G, L, M, P)
— Did the sodium hydroxide have to be in an aqueous solution?	None	Dr. Bowman Report, Affidavit; Dr. Weiner Reports, Affidavit; (Exs. D, E, F, L, M, P)
Would it be "clearly evident" to a skilled chemist how to correct the error?	Attorney Argument (Watson Br., at 20-22; Paddock Br., at 33-38)	Dr. Bowman Report, Affidavit; Dr. Weiner Reports, Affidavit; (Exs. D, E, F, L, M, P)
— Would a skilled chemist correct the claim by using a concentration other than "0.1 N"?	Attorney Argument (Paddock Br., at 34-37)	Dr. Bowman Report, Affidavit; Dr. Weiner Reports, Affidavit; (Exs. D, E, F, L, M, P)

The Federal Circuit has long held that issues involving differences of scientific opinion or expert credibility cannot be resolved on summary judgment. *See, e.g., Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1578 (Fed. Cir. 1991). For example, in *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 885 (Fed. Cir. 1998), the Court vacated a summary judgment ruling where the record contained conflicting expert and fact witness affidavits on material issues relating to the alleged obviousness of the claimed invention. *Monarch Knitting*, 139 F.3d at 885. Likewise, in *Abbott Labs. v. Torpharm, Inc.*, 300 F.3d 1367, 1377 (Fed. Cir. 2002), the Court vacated a summary judgment ruling where the record contained conflicting expert affidavits dealing with infringement issues.

Similarly, in this case, when the evidence is viewed in the light most favorable to Plaintiffs, and all reasonable inferences are drawn in Plaintiffs' favor, it creates numerous issues of material fact precluding summary judgment. This is particularly true in light of Defendants' burden to show by clear and convincing evidence that a skilled chemist would not understand how to correct the error in the original sodium hydroxide concentration. *Arthrocare*, 406 F.3d at 1375.

IX. THE CERTIFICATE APPLIES TO THIS LITIGATION

In its summary judgment brief, Watson concedes that if the Certificate of Correction is not invalid, it applies to the instant litigation. Paddock, however, disputes this contention.

It is well-settled that a Certificate of Correction is only effective for causes of action arising after the Certificate has issued. *Southwest Software,* 226 F.3d at 1294. In this case, Plaintiffs filed their request for a Certificate of Correction *before* they filed the instant lawsuit or even knew that the two Defendants were planning to market a generic version of AndroGel®. (*See* Ex. O). The PTO, however, did not actually issue the Certificate until December 16, 2003 – four months after Plaintiffs filed the complaints in the instant case. (Ex. H). Based on these facts, Paddock asserts that the Certificate of Correction does not apply to this litigation.

This argument misconceives the nature of Plaintiffs' action, which is not an action for damages based on past acts of infringement. Rather, this action arises under the Hatch-Waxman Act, which focuses on *future* acts of infringement. *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247-50 (Fed. Cir. 2000). To be sure, the statute provides that the filing of an ANDA is itself considered an artificial act of infringement. 35 U.S.C. § 271 (e)(2)(A). This "act,"

however, is merely a vehicle to provide the court with jurisdiction so that it can resolve a "dispute concerning *an infringement that will happen in the future*." *Bayer AG*, 212 F.3d at 1249 (emphasis added). In particular, the focus of the infringement inquiry under the statute is on the "product that will be sold *after* the FDA's approval of the ANDA." *Id*. (emphasis added). In this case, for example, Plaintiffs seek to enjoin Defendants from selling any generic form of AndroGel® after Defendants have obtained the necessary FDA approval – which will necessarily occur long after the December 16, 2003 issuance of the Certificate of Correction.

Consequently, in determining whether an injunction should issue, the Court must determine whether Defendants' *future* sales will infringe the then-existing patent – *i.e*., the patent as corrected by the December 16, 2003 Certificate of Correction. This follows from the well-settled rule that each sale of an infringing product constitutes a separate cause of action that does not arise until the sale has actually occurred.[10] Because the cause of action will not arise until the date of the

[10] *Augustine Med., Inc. v. Progressive Dynamics, Inc.*, 194 F.3d 1367, 1371 (Fed. Cir. 1999); *Johns Hopkins Univ. v. Cellpro, Inc*., 152 F.3d 1342, 1366 (Fed. Cir. 1998); *A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020, 1031 (Fed. Cir. 1992).

future sale, the infringement inquiry must be based on the then-existing patent — *i.e.*, the patent as corrected.

Furthermore, even if this action did not relate to future acts of infringement, the Certificate of Correction would still be applicable. The courts have long held that patent infringement is a continuing tort. *Augustine Med.*, 194 F.3d at 1371; *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1221-22 (Fed. Cir. 1995). Consistent with these holdings, the Federal Circuit has made clear that a course of conduct can become culpable even if it originally begins as an "innocent" action – *and even if it becomes culpable only after a lawsuit is filed*:

> [P]atent infringement is a continuing tort, and an action even if innocently begun does not automatically retain its purity as circumstances change. *The filing of a lawsuit does not stop the clock insofar as culpability may arise from continuing disregard of the legal rights of the patentee*.

Pall Corp., 66 F.3d at 1221-22 (emphasis added).

The same rationale applies here, particularly since Defendants have continued to pursue their ANDAs in disregard of Plaintiffs' legal rights. (*See*, *e.g.*, Exs. J, K). For example, Paddock submitted six amendments to its ANDA between April 8 and October 22, 2004, while Watson submitted amendments on December 30, 2003 and June 30 and September 17, 2004. (*Id.*). Accordingly, the Certificate of Correction applies to Defendants' continuing infringement of

Plaintiffs' patent in the period following the issuance of the Certificate on December 16, 2003.

X. EVEN IF THE CERTIFICATE DID NOT APPLY TO THIS CASE, THE COURT CAN CORRECT THE ERROR

Even if the Certificate of Correction did not apply to the instant action, the underlying error is so basic – and so obvious – that it can be readily corrected by this Court. For more than 80 years, the courts have corrected typographical or clerical errors in patents when such errors were apparent in light of the claims, the specification and the file history. *I.T.S. Rubber Co. v. Essex Rubber Co.*, 272 U.S. 429, 442 (1926); *Lemelson v. General Mills, Inc.*, 968 F.2d 1202, 1204 n.3 (Fed. Cir. 1992); *Novo Indus., L.P. v. Micro Molds Corp.*, 350 F.3d 1348, 1356-57 (Fed. Cir. 2003). In these cases, the courts have held that a trial judge can correct a patent when two conditions are met: (1) the correction is not subject to reasonable debate based on the claim language and the specification; and (2) the prosecution history does not suggest a different interpretation of the claims. *Novo,* 350 F.3d at 1357.

Both conditions are met here. There can be no "reasonable debate" that (1) the original designation of "about 1% to about 5%" (or "about 1% to about 3%") sodium hydroxide was an error; and (2) the error "should appropriately be corrected" by inserting the term "0.1 N" before the phrase "sodium hydroxide."

To be sure, as noted earlier, Defendants assert that the concentration of sodium hydroxide can be expressed in a variety of ways. This argument, however, ignores the clear teachings of the preferred embodiment and the specification which expressly refer to a solution of "0.1 N sodium hydroxide." (Ex. A, 13:32). As shown earlier, a skilled artisan would not disregard the specification in determining how to correct the error. (Ex. E, at ¶ 7).

Nor does the prosecution history suggest a different interpretation of the claims. On the contrary, as noted above, the prosecution history makes unmistakably clear that the applicants *intended* to claim a range that included the concentration of sodium hydroxide in the AndroGel® formulation. (*See* p. 29, *supra*). This was also the understanding of the Examiner, who plainly construed the claims to cover AndroGel®. (Ex. N). Finally, the specification discloses how the ministerial error could be corrected – *i.e.*, by simply inserting the term "0.1 N" before "sodium hydroxide," as shown by the specification.

In light of these facts, this Court can make the same correction that the PTO did by construing Claims 1, 9, 10 and 18 to include the term "0.1 N" before the phrase "sodium hydroxide." Indeed, the very fact that the PTO issued the correction provides independent support for this Court to do the same thing.

XI. CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that this Court deny Defendants' motions for partial summary judgment.

Dated: October 17, 2005

Respectfully submitted,

UNIMED PHARMACEUTICALS, INC. and LABORATORIES BESINS ISCOVESCO

By: /s/ James R. Ferguson
One of their attorneys

Jerry B. Blackstock Georgia Bar No. 061000
HUNTON & WILLIAMS
4100 Bank of America Plaza
600 Peachtree Street NE
Atlanta, Georgia 30308-2216
Telephone: (404) 888-4000
Facsimile: (404) 888-4190

James R. Ferguson
MAYER, BROWN, ROWE & MAW LLP
71 South Wacker Drive
Chicago, Illinois 60606
Telephone: (312) 782-0600
Facsimile: (312) 701-7711

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

UNIMED PHARMACEUTICALS, INC., a Delaware corporation, and LABORATORIES BESINS ISCOVESCO, a Delaware corporation, Plaintiffs,	)	
v.	)	**Nos. 1:03-CV-2501 TWT** **1:03-CV-2503 TWT**
WATSON PHARMACEUTICALS, INC., a Nevada corporation, and PADDOCK LABORATORIES, INC., a Minnesota corporation, Defendants.	)	

CERTIFICATE OF SERVICE

I hereby certify that on October 17, 2005, a true and correct copy of the foregoing document was filed electronically via CM/ECF in the United States District Court for the Northern District of Georgia, with notice of same being electronically served by the Court, addressed to:

David A. Rabin Morris, Manning & Martin LLP 1600 Atlanta Financial Center 3343 Peachtree Road, N.E. Atlanta, Georgia 30326-1044 ***Attorneys for the Defendant Watson Pharmaceuticals, Inc.***	Barry S. White Frommer, Lawrence & Haug LLP 745 Fifth Avenue New York, New York 10151 ***Attorneys for the Defendant Watson Pharmaceuticals, Inc.***
Mark G. Trigg Ernest L. Greer Hayden Pace Greenberg Traurig, LLP The Forum Suite 400 3290 Northside Parkway, N.W. Atlanta, Georgia 30327 ***Attorneys for the Defendant Paddock Laboratories, Inc.***	Albert L. Jacobs, Jr. Daniel A. Ladow Greenberg Traurig, LLP MetLife Building 200 Park Avenue New York, NY 10166 ***Attorneys for the Defendant Paddock Laboratories, Inc.***

DATED: October 17, 2005 By: /s/ James R. Ferguson